Claim 8 has been added directed to the portion of SEQ. ID 1 as set forth at page 12, line 15 of the application as filed.

With respect to the objection of claim 1 at the top of page 2 of the Office Action, the amendment as suggested by the Examiner has been made.

At pages 2-3 of the Office Action, the Examiner sets forth claim rejections under the second paragraph of 35 U.S.C. § 112.

First of all, the Examiner submits claims 1-7 are indefinite because the invention is claimed in the plural. Appropriate correction has been made.

Next, claims 4 and 5 are said to be unclear regarding the use of the word "gene" following the word "promoter". Amended claim 1 has been written taking this point into account.

Next, with respect to claim 4, the Examiner submits that the function of the pMCP promoter is not clear. In rewriting claim 1, the purpose of the promoter in promoting the human complement inhibitor has been set forth.

Next, the Examiner objected to the phrase "or its parts" in claim 5. Applicants in amending claim 1, have used the singular language and defined the part in accordance with its function. One specific part as set forth at page 4, line 15 of the application is now set forth in new claim 8.

Finally, the last point raised by the Examiner regarded the use of "comprising" type language. In rewriting the claims, "comprising" type language has been employed.

From the above, Applicants submit that all 35 U.S.C. § 112 second paragraph rejections have been obviated.

Beginning towards the bottom of page 3 of the Office Action, and carrying over through the middle of page 8 of the Office Action, the Examiner has raised claim rejections under the first paragraph of 35 U.S.C. § 112.

The basic position of the Examiner appears to be that the specification is not enabling for the claims as presented. In this regard, the Examiner submits that the claims define an invention in which a transgenic mammal containing the human DAF/CD55 gene is capable of expressing it at a level sufficient to prevent hyperacute rejection of xenotransplanted organs from the same transgenic mammal donors. The Examiner submits that no other purpose for these transgenic mammals would be apparent. The Examiner goes on to note the in vitro erythrocyte lysis data but submits that this cannot be correlated with suppression of hyperacute rejection in a transplantation recipient of a DAF/CD55 organ.

First of all, Applicants' claims do not recite that the claimed mammal must be used for xenotransplantation. The enablement requirement of 35 U.S.C. § 112, first paragraph, only requires that the specification teach how to make and use the claimed subject matter. Certainly, here there is no issue on how to make the transgenic non-human mammal as claimed. With respect to how to use it, this requirement is often considered synonomous with the utility requirement of the statute. Any demonstrated utility or any utility accepted by the skilled artisan from understanding the disclosure in view of the prior art is sufficient.

In the present application, Applicants list six main industrial applicabilities of the present clamed invention, beginning at the bottom of page 9 over through page 11 of the application as filed. Items (1) through (4) relate to use of the animal models in developing further technology in the area of xenotransplantation and in order to study the effects of combinations of complement inhibitors. These are very real utilities for an animal model, which animal is what is being claimed. The use of the animal model in a research environment is itself a sufficient use and utility.

In addition to the above, industrial applicability (6) regards the use of cells from the organs of the animal models as claimed for ex vivo use to supplement or substitute for functions of damaged organs or cells of patients. The results of Fig. 7 regarding transgenic mammal erythrocytes are supportive of industrial applicability (6). In other words, Applicants establish avoidance of an ex vivo hyperacute rejection.

From the above, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph rejection. Applicants' claims are fully enabled by the application as filed. Furthermore, the skilled artisan would accept that the scope of the invention as claimed will be useful with respect to mammals other than transgenic pigs and transgenic mice.

At pages 8-9 of the Office Action, claims 1-3, 6 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rosengard et al.

At pages 9-11 of the application as filed, claims 1 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosengard et al. in view of Toyomura et al.

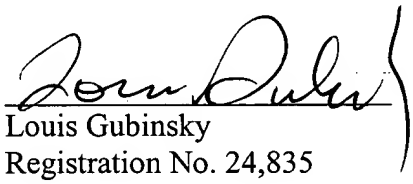
At this time, Applicants have inserted the subject matter of claims 4 and 5 into claim 1. In this regard, the promoter is SEQ. ID No. 1 or part thereof. The Examiner cites the abstract, (the last three lines) of Toyomura as suggesting the pMCP promotor can be used for expression of human complement inhibitor in pigs to reduce observed rejection in pig to human organ transplanation. From this, the Examiner concludes that it would have been obvious to modify the transgenic pig of Rosengard to use pMCP to direct expression of hDAF/CD55 in transgenic mammals with a reasonable expectation of success.

First of all, there is no question that Rosengard does not disclose a promoter of the porcine complement inhibitor (pMCP) defined by SEQ. ID No. 1 of the present application. Furthermore, the common assignee of Toyomura also advises that Toyomura et al. does not disclose such a promoter. Accordingly, claim 1 is both novel and unobvious over the prior art.

Early indication of allowability is respectfully requested. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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